IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ROXANE LABORATORIES, INC., Plaintiff, v. NOVEL LABORATORIES, INC. and GAVIS PHARMACEUTICALS, LLC, Defendants.	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Roxane Laboratories, Inc. ("Roxane"), for its Complaint against Defendants Novel Laboratories, Inc. ("Novel") and Gavis Pharmaceuticals, LLC ("Gavis") (collectively, "Defendants), alleges as follows:

PARTIES

1. Roxane is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

2. Upon information and belief, Novel is a corporation organized and existing under the laws of Delaware, having its principal place of business at 390 Campus Drive, Somerset, New Jersey 08873.

3. Upon information and belief, Gavis is a corporation organized under the laws of Delaware, having its principal place of business at 400 Campus Drive, Somerset, NJ 08873.

4. Upon information and belief, Novel conducts business, individually and/or jointly with its affiliate Gavis, with respect to regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in the

state of New Jersey. For example, Gavis's and Novel's website, http://www.gavispharma.com/about/novel-labs/, states that, "[t]ogether Novel Laboratories and GAVIS® Pharmaceuticals offer the complete package: formulation, development, manufacturing, packaging, sales, marketing, and distribution."

NATURE OF ACTION

5. This is a civil action for declaratory and injunctive relief against Defendants for infringement of United States Patent No. 8,563,032 ("the '032 Patent"), arising from Novel's submission of Abbreviated New Drug Application ("ANDA") No. 20-7525 to the United States Food and Drug Administration ("FDA") for approval to market a generic calcium acetate capsule drug product ("the Accused Product") and Defendants' intent to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Accused Product in the United States imminently upon FDA approval to do so.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action because it arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has personal jurisdiction over Defendants because, upon information and belief, *inter alia*, Defendants each have their principal place of business in New Jersey; each are registered to, and do, conduct business in New Jersey; each have availed themselves of the rights and benefits of New Jersey Law; and each have engaged in substantial and continuing contacts with New Jersey.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

9. On October 22, 2013, the United States Patent and Trademark Office lawfully issued the '032 Patent, entitled "Formulation and Manufacturing Process for Calcium Acetate Capsules." A true and correct copy of the '032 Patent is attached hereto as Exhibit A. Roxane is the record owner of the '032 Patent by assignment.

10. The '032 Patent claims, *inter alia*, novel formulations of calcium acetate capsules. Calcium acetate capsules are used to control hyperphosphatemia in patients suffering from end stage renal failure.

ROXANE'S GENERIC CALCIUM ACETATE CAPSULE PRODUCT

11. Roxane submitted ANDA No. 77-728 to the FDA to market a generic form of calcium acetate capsules (the "Roxane Calcium Acetate Capsule Product") for the reduction of serum phosphorous in patients with end stage renal disease. The inventions disclosed in the '032 Patent arose out of Roxane's substantial and successful effort to develop the Roxane Calcium Acetate Capsule Product. Roxane's patented Calcium Acetate Capsule Product comprises flowable granules of calcium acetate within a capsule that is designated size 00.

12. The FDA approved Roxane's ANDA No. 77-728 in 2008, and thereafter, Roxane began marketing the Roxane Calcium Acetate Capsule Product.

DEFENDANT'S GENERIC CALCIUM ACETATE CAPSULE PRODUCT

13. Upon information and belief, Novel filed ANDA No. 20-7525 seeking FDA approval for the Accused Product.

14. Upon information and belief, Novel included within its ANDA a Paragraph IV certification stating that at least United States Patent No. 6,576,665, which is listed in the Orange

Book as covering PhosLo®, the Reference Listed Drug for the Accused Product, is invalid or not infringed by the Accused Product.

15. Upon information and belief, by filing ANDA No. 20-7525 and a Paragraph IV certification, Novel evidenced that it intends to, and will, engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Accused Product promptly upon receiving FDA approval to do so.

16. Upon FDA approval of Novel's ANDA No. 20-7525, Defendants will infringe one or more claims of the '032 Patent by making, offering to sell, selling, or importing the Accused Product in the United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

17. Defendants have been on constructive notice that their planned commercial launch of the Accused Product likely would infringe Roxane's '032 Patent since the '032 Patent issued on October 22, 2013.

18. Novel received actual notice of the '032 Patent on or about April 16, 2015.

19. Roxane sought samples of the Accused Product and any other information that would assist in confirming that the Accused Product is within the scope of at least one claim of the '032 Patent.

20. In response to Roxane's requests, Defendants provided to Roxane information purporting to describe the Accused Product under the protection of a confidentiality agreement, stating that such disclosure was for the limited purpose of evaluating the Accused Product. Defendants also stated that Roxane was to destroy or return any such information provided by Defendants by a date certain, unless Roxane commenced a patent infringement lawsuit against

Defendants by such date certain. This lawsuit follows the receipt of such information pursuant to said agreement.

COUNT ONE
(Infringement of U.S. Patent No. 8,563,032)

21. Roxane reasserts and realleges Paragraphs 1-20 above as if fully set forth herein.

22. Upon information and belief, Defendants intend to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accused Product promptly upon receiving FDA approval to do so.

23. Upon information and belief, Defendants intend to engage in such infringing conduct imminently.

24. The commercial manufacture, use, importation, offer for sale, and/or sale of the Accused Product would infringe one or more claims of the ’032 Patent.

25. Defendants have had constructive notice of the ’032 Patent since the ’032 Patent issued on October 22, 2013.

26. Defendants have had actual notice of the ’032 Patent since on or about April 16, 2015, before the filing of this action, and have continued their efforts to bring the Accused Product to market in the United States despite an objectively high likelihood that such actions constitute infringement of a valid patent.

27. There is a justiciable controversy between the parties hereto as to infringement of the ’032 Patent. By way of example, the submission of ANDA No. 20-7525 to the FDA constitutes activity directed toward infringement of a valid patent and a refusal to change course in the face of acts sufficient to create reasonable apprehension of forthcoming suit. Accordingly, there is a sufficient case or controversy under the Declaratory Judgment Act.

28. Upon information and belief, Defendants' infringement of the '032 Patent will be willful, deliberate, and intentional, and thus any manufacturing, sale, offer to sell, marketing, or importation of the Accused Product in the United States will demonstrate a reckless disregard of Roxane's patent rights.

29. Roxane will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Roxane does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Roxane respectfully requests the following relief:

A. A judgment that Defendants' making, using, selling, offering to sell, or importing of the Accused Product will infringe the '032 Patent;

B. A judgment providing that the effective date of any FDA approval to make, use, offer for sale, and/or sell the Accused Product be no earlier than the expiration of the '032 Patent;

C. A preliminary and permanent injunction restraining and enjoining Defendants, their officers, agents, attorneys, servants, employees, and all persons in active concert or participation with them, from making, using, selling, offering to sell, or importing the Accused Product until after the expiration of the '032 Patent;

D. If Defendants engage in the commercial manufacture, use, offer to sell, sale, or importation of the Accused Product prior to the expiration of the '032 Patent, a judgment awarding Roxane damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

E. An order declaring that Defendants' infringement is and/or will be willful, warranting increased damages under 35 U.S.C. § 284;

F. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

G. An award of costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

Dated: July 17, 2015

Respectfully submitted,

/s/ Beth S. Rose

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